


Standard Operating Procedure		
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Approved by: Doug Leonard	Revision 17 Date: 09/02/11	Page 1 of 12

POLICY / POLICY REFERENCE

L-A-B Quality System Manual
ISO/IEC 17011
ISO/IEC 17025

ACCEPTED/FILED

AUG 26 2013

Federal Communications Commission
Office of the Secretary

DEFINITIONS

IAW = In Accordance With

PURPOSE & SCOPE

This procedure defines the method used to prepare for and conduct a laboratory assessment. This procedure applies to L-A-B, the lead assessor, and members of the assessment team. The documents referenced in this SOP represent L-A-B's core documents for ISO/IEC 17025 Accreditation. Other documents may be utilized for sector specific programs.

RESPONSIBILITY

L-A-B staff, lead assessor, and members of the assessment team are responsible for ensuring that all functions of this procedure are fulfilled.

PROCEDURE**A. Activities to be Carried out Prior to Assessment Visit**

Form 28 – Application for Accreditation

Policy 004 – Delays Caused by Applicant and Client

L-A-B SOP 214 – Surveillance Preparation and Procedure

Form 18 - Full Assessment Documentation Checklist (or Program Specific Document Checklist)


Form 214.4 - Surveillance Assessment Documentation Checklist

Form 218.5 – Accreditation Tracking for Calibration

Form 218.6 – Accreditation Tracking for Testing

Form 001 – Traceability Tracking

- 1) Form 28 - Application for Accreditation shall be filled out and approved (Initial Assessment Only).
- 2) Surveillance assessment activities are detailed in, L-A-B SOP 214 Surveillance Preparation and Procedure.
- 3) L-A-B shall contact the client to instruct them on their responsibilities for the assessment process which includes:
 - a) Assigning a responsible, knowledgeable person from the client's organization as a point of contact.

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- b) Submitting the required documentation detailed in L-A-B Form 18 and Form 214.4 and/or the appropriate required documentation as specified per accreditation program (i.e. DoD ELAP, NEFAP, METCAP, CMT LAP, etc.)
- c) Meeting the requirements of Policy 004 - Delays Caused by Applicant and Client
- d) Within the event letter L-A-B also sends the client an assessor(s) bio(s) with the request for sign off assuring no conflict with the assessor(s).
- 4) The Appropriate L-A-B Manager shall assign the Lead Assessor, Team Assessor(s), and Technical Experts by reviewing the laboratories proposed scope of accreditation or current scope of accreditation and the laboratories completed Form 001 - Traceability Tracking to determine the technical competence necessary to perform the assessment. This information will then be compared with the assessors completed Form 209.4 – Assessor Major Field and Discipline rating form and the specific scopes on the L-A-B assessor database to assure the appropriate technical competence is available to perform the assessment. The Program Manager may utilize the rating system from the Form 209.4 along with the rating system as defined in SOP 105 to determine the appropriate assessor's competence.
- 5) L-A-B shall send to the lead assessor the following information in order that they may develop an appropriate assessment plan:

For Initial Assessment and Full-Reassessments

- a) Client contact information.
- b) Proposed Scope of Accreditation.
- c) Allocation Sheet with the estimated days for the assessment.
- d) Form 218.5 / 218.6 – Accreditation Tracking.
- e) Form 001 - Traceability Tracking.
- f) Prior years Form 14 – Assessment Report
- g) Prior years Form 33 – Non-Compliance Report
- h) L-A-B approved client documentation.

For Surveillance Assessments

- a) Client contact information.
- b) Proposed Scope of Accreditation.
- c) Allocation Sheet with the estimated days for the assessment.
- d) Form 218.5 / 218.6 – Accreditation Tracking.
- e) Form 001 - Traceability Tracking.
- f) Prior years Form 14 – Assessment Report
- g) Prior years Form 33 – Non-Compliance Report

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h) L-A-B approved client documentation.

B. Assessment Plan

FORM 305 Series - Assessment Plan

Form 205.5 – Assessment Matrix

L-A-B Policy 010 - Technical Competence Evaluation for Laboratories


L-A-B Policy 009 - Accreditation of Multiple-Site Laboratories

Form 218.5 / 218.6 – Accreditation Tracking

Form 001 – Traceability Tracking

Manual 006 Assessor Handbook

- 1) The lead assessor, with the help of the other assessment team members, shall prepare an assessment plan on the appropriate L-A-B assessment plan form and submit to L-A-B Headquarters a minimum of four weeks prior to the assessment date. The completed plan shall be sent to the client for approval prior to the date of the assessment.
 - a) The plan for a Pre-assessment shall include brief coverage of all elements of ISO/IEC 17025.
 - b) Form 218.5 / 218.6 and Form 001 shall be used when developing the assessment plan to assure the appropriate technical witnessing may take place.
 - c) The plan for an Initial and Full Assessments shall include thorough coverage of all elements of ISO/IEC 17025, along with an in-depth assessment of the laboratory's technical competency. Technical competency shall include a plan to witness calibrations / tests at the laboratories clients (on-site witnessing) per the requirements of L-A-B Policy 010 - Technical Competence Evaluation for Laboratories.
 - d) The plan for a Surveillance Visit shall include coverage of the appropriate elements of ISO/IEC 17025 per Surveillance Matrix Form 205.5, along with a sample assessment of the laboratory's technical competency. The plan shall also include verification of implementation of past corrective actions. On-site witnessing shall also be considered per the requirements of L-A-B Policy 010 - Technical Competence Evaluation for Laboratories.
 - e) Assessment plans for Multi-site assessments must meet the requirements of L-A-B Policy 009 - Accreditation of Multiple-Site Laboratories.

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C. Instructions for *Client Use* of Form 48B - Assessor/Client Checklist

L-A-B SOP 209.2 – Instruction Guidelines for the use of Form 48B

- 1) A complete Form 48B shall be sent to the Ft. Wayne Headquarters Office by the laboratory prior to *pre-assessment, initial assessment, or full-reassessment*.
 - a) The client can get Form 48B from the L-A-B Website at: www.l-a-b.com
 - b) The client shall complete the form and e-mail it to the Operations Office, along with all supporting documentation referenced in the Form 48B.
 - c) L-A-B shall use the Form 48B completed by the laboratory to conduct the documentation review, and the assessors shall use it to document the facility assessment of the laboratory.

D. Instructions for Documentation Review

- 1) The document review process will occur in two phases. First phase at the Headquarters Office of L-A-B and the second phase with the appropriate assessor prior to the assessment.
- 2) The first phase of the review will be performed at L-A-B Headquarters and will assure the receipt of:
 - a) The proposed scope of accreditation.
 - b) The supporting uncertainty budgets.
 - c) The procedure for proficiency testing and the results of that test
 - d) The existence of the appropriate documents for the second phase of the document review.
- 3) The second phase of the review will be performed by the Lead Assessor and shall include:
 - a) Evaluation of the Form 48B "Assessor / Client Checklist" for compliance with the requirements of ISO/IEC 17025 and L-A-B's Policies and Procedures in comparison to the client supplied documents. The Assessor shall complete the "Doc Review / Pre Assessment Notes" column on Form 48B.
 - b) Further evaluation of the client's scope and uncertainty budgets for calibration laboratory assessments, and as needed for testing laboratory assessments to ready a full critique at the level of uncertainty for the future witnessed technical competence by the client.
 - c) Review the Management Review and Internal Audits.

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- d) Review the PT / ILC procedure and results for satisfactory participation and the corrective action if needed.
- 4) The lead assessor shall inform the client of any observations or requirements the laboratory may need to address prior to the assessment.

E. Pre-Assessment

- 1) A pre-assessment is a brief look at the clients Quality Management System that assesses the laboratory's preparedness for the accreditation process.
- 2) The assessor shall submit an assessment plan to L-A-B Headquarters for client approval prior to the pre assessment.
- 3) The lead assessor must complete the document review for the client prior to the Pre-assessment. The lead assessor shall look at evidence of compliance with the 17025 standard, the requirements of L-A-B, and with the documented procedures of the laboratory.
- 4) Where possible in the allotted time, the lead assessor shall briefly examine the laboratory's technical capabilities.
- 5) The lead assessor shall document non-compliances noted during the pre-assessment.
- 6) The laboratory shall correct all non-compliances and document the actions take using their corrective action procedure prior to the assessment visit.
- 7) Quality System Review & Assessment Checklist or equivalent pre assessment report and Form 14 – Assessment summary and obtain a laboratory representatives signature. The Form 14 shall then be sent to L-A-B and Form 32 Participants List to L-A-B.

F. Activities to be Carried out during the Assessment

Instructions for Assessment Process

Form 32 - Participant's List

Form 205.2 - Opening Meeting minutes (also included in the assessment plan)

Form 48B - Quality System Review & Assessment Checklist

Form 214.2 - Type I Surveillance Checklist


Form 214.3 - Type II Surveillance Checklist

Form 205.1 – Technical Competence Evaluation

Form 33 – Non-Conformance Report

Form 14 – Assessment Report

Manual 006 - Assessor Handbook

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Team Meeting Prior to the Assessment

- 1) If more than one assessor is assigned to the assessment, the team shall have a meeting prior to beginning the assessment. The following should be considered at this meeting:
 - a) How the specific responsibilities for activities will be assigned to each assessor. If a conflict arises during this process, the lead assessor shall make the final decision.
 - b) Techniques for accomplishing the full agenda in the allotted time.
 - c) Any concerns that the Lead Assessor has which were discovered during the document review. He should advise the assessors of any areas that he feels should have special attention during the assessment process.
 - d) Any pre-assessment results shall be discussed, and those areas of weakness discovered shall be covered. The assessor assigned to a specific task shall investigate any pre-assessment corrective actions for evidence of appropriate implementation and compliance with proposed actions. The assessor shall evaluate effectiveness of the proposed actions in preventing a recurrence of the same or similar problems.
 - e) The team should agree on the starting times, daily wrap up times, and final briefing time.

Opening Meeting

Form 205.2 - Opening Meeting minutes
Manual 006 - Assessor Handbook

- 1) A formal opening meeting is held at the beginning of the assessment. The meeting attendees should be the assessment team, at least the client contact, and any other client members responsible for quality or technical aspects of the laboratory or other staff wishing to be present. Other attendees that should be present are the management from the areas that will be evaluated during the assessment. A Form 32 - Participants list shall be circulated to obtain a record of individuals present during any part of the assessment.
- 2) The opening meeting shall be conducted IAW with Form 205.2 - Opening Meeting minutes or the approved Assessment Plan Agenda (which incorporates the Form 205.2 requirements)
- 3) For multisite assessments, a kickoff meeting should be performed at the start of each site. A participants list must be circulated.

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Assessment Process

Form 48B - Quality System Review & Assessment Checklist

Form 214.2 - Type I Surveillance Checklist

Form 214.3 - Type II Surveillance Checklist


Form 33 – Non-Conformance Report

Manual 006 - Assessor Handbook

- 1) The assessment process shall confirm the client's compliance or otherwise with the requirements of ISO/IEC 17025, L-A-B accreditation requirements, and the laboratory's own procedures by examining objective evidence. The assessment process also verifies the technical competence of the laboratory to perform all test / calibration technology / parameter listed on the proposed Scope of Accreditation.
- 2) For Initial and Full Reassessments the assessor shall complete a Form 48B providing details of compliance. Assessor should indicate any areas of Non-Compliance, areas that require improvement, and where exceptionally good practices exist. It is extremely important that the Assessor comment on the laboratory's compliance of the standard.
- 3) For Surveillance Assessments the assessor shall complete the appropriate Form 214.2 or 214.3 providing details of compliance. Assessor should indicate any areas of Non-Compliance, areas that require improvement, and where exceptionally good practices exist. It is extremely important that the Assessor comment on the laboratory's compliance of the standard.
- 4) The assessors should discuss any negative findings with the client representative at the time they are discovered. Any Non-Compliance's shall be documented on L-A-B Form 33 – Non-Compliance Report. Assessor must provide specific details of the noncompliance citing against a specific element of ISO/IEC17025, L-A-B policies and procedures, or the laboratories own quality system documentation.

G. Instructions for Technical Assessment

- 1) While the Form 48B provides the checklist for evaluating the client documentation of their system, it does not provide adequate evidence for the technical evaluation of the laboratory's ability to perform the specific tests or calibrations on the proposed Scope of Accreditation. The Assessors assigned to do the technical assessments are responsible for completing the Form 205.1 - Technical Competence Assessment checklist. The evaluations should be performed with the following in mind:
 - a) The evaluation shall verify the laboratory's ability to perform the test or calibration competently including those calibrations/tests performed on-

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site or in the lab per L-A-B Policy 010 – Technical Competence Evaluation for Laboratories.

- b) The evaluation shall include verification of the laboratory equipment's compliance with the test method(s).
- c) The equipments calibration and maintenance status, and functionality.
- d) The competence of the personnel performing the test and evaluating the results.
- e) Where appropriate, the laboratory-developed method's compliance with a recognized test method where appropriate, or else method validation.
- f) Form 001 "Traceability Tracking" shall be reviewed with the client and modified if required to assure appropriate documentation of the laboratories traceability.


H. Instructions for use of Form 205.1 – Technical Competence Assessment

Form 205.1 – Technical Competence Evaluation

Form 230 – Uncertainty Budget Checksheet

Manual 006 - Assessor Handbook

- 1) L-A-B shall send a copy of the client's proposed Scope of Accreditation to the assessment team members.
- 2) It is the assessor's responsibility to assure that the laboratory is competent to perform ALL of the tests/calibrations that are specified on their proposed Scope. During the witness the uncertainty shall be challenged against the supplied budget (see Annex A of the assessor handbook or Form 230 – Uncertainty Budget Checksheet for guidance).
- 3) The laboratory is responsible for providing the samples for the tests that are on their proposed scope. The assessor must witness all test/calibration technologies/parameters that the laboratory wishes to have on their Scope of Accreditation.
- 4) Form 205.1, highlights the important factors from ISO/IEC 17025 that should be verified for each test / calibration technology / parameter. The assessor is responsible for verifying the specific test/calibration technology/parameter to assure that the laboratory is performing the witnessed test / calibration correctly.
- 5) For on-site witnessing the column shall be marked appropriately with the location and relevant information in the notes.

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- 6) For in-house calibrations, the column shall be marked appropriately to indicate that the laboratory meets the requirements of L-A-B Policy 010 Technical Competence Evaluation for Laboratories.
- 7) Assessor must complete and submit to L-A-B a Form 205.1 – Technical Competence Assessment for every assessment.

I. Instruction for Verification of the Client's Scope of Accreditation


- 1) The L-A-B Technical Staff and Lead Assessor and / or qualified technical assessors shall evaluate the clients Scope of Accreditation. The evaluation shall include but is not limited to:
 - a) The laboratory's ability to perform the test / calibrations listed on the Scope.
 - b) The validity of the Best Measurement Capability stated by the laboratory. This should include the evaluation of the method used to determine the Best Measurement Capability and the uncertainty budgets, and supporting experimental evidence. (Utilize Annex A of the Assessor handbook or Form 230 – Uncertainty Budget Checksheet as guidance in assessing the BMC on the scope).
 - c) The laboratory's ability to test / calibrate all items and materials specified on the Scope.
 - d) Any discrepancies between the Scope and the assessors' evaluation shall be settled prior to the end of the assessment visit.
 - e) The lead assessor shall sign and have the client sign the agreed-upon Scope of Accreditation and include it in the technical package submittal.

Daily Debriefing

- 1) Each day prior to leaving the client's facility, the assessment team shall conduct a meeting with at a minimum the client contact. The team shall discuss the findings that they had on this day, and allow the client to present any information that may be necessary to clarify findings made during the assessment activities. The client should not be surprised on the last assessment day by previously undisclosed negative findings presented during the closing meeting.

Final Team Meeting Minutes

- 1) On the final day of the assessment, the team shall meet prior to the Closing Meeting to discuss their assessment findings. They shall prepare

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the draft findings of the assessment and shall prepare the Corrective Action Request that shall be given to the client prior to leaving.

- 2) After completion of the assessment for each site, the assessment team shall meet to discuss the findings of the assessment for that site. If more than one checklist was used by the assessment team, the lead assessor, with the aid from the other assessors, shall pull together the checklists into one report that defines compliance of the laboratory with the accreditation requirements.
- 3) ***The notes taken during the assessment process are critical to making a decision about granting accreditation. The assessors should take good notes to help prepare the summary for the client and L-A-B.***

Closing Meeting Minutes

- 1) The Closing Meeting is to be carried out. The Form 14 – Accreditation Report is to be utilized as the closing meeting minutes form.

J. Post Assessment Activities

L-A-B Policy 008 – Timely Submittal of Assessment Documentation and Assessor Payment
Form 205 - Assessor Documentation Checklist
L-A-B SOP 218 – Technical Package Review
Manual 006 - Assessor Handbook


Assessor Instructions

The lead assessor is responsible for completing and preparing the Technical Package submittal in accordance with Policy 008 - Timely Submittal of Assessment Documentation and Assessor Payment.

L-A-B Instructions

L-A-B is responsible for the assessment technical package review and approval per L-A-B SOP 218 – Technical Package Review.

L-A-B to complete all post assessment activities including the completion of the LACC (Form 18.2) and the ISR (Form 20) to assure proper closure of an event (project).

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REVISION HISTORY

Revision Level	Revision Date	Revised By	Brief Description of Revision
Original Issue	7/12/00	Lynne Neumann	Original Issue
Rev. 1	10/12/00	Lynne Neumann	Applied new format. Removed duplicative language and clarified assessors responsibility for interface with client. Defined IAW. Included Post Assessment section that includes what to send to L-A-B to document assessment. Added closing meeting minutes
Rev. 2	11/30/00	Lynne Neumann	Added requirement that scheduled assessments be mutually acceptable. Defined documents to go to lead assessment when appointed.
Rev. 3	5/29/01	Lynne Neumann	Clarified requirements, standardized on Non-Conformance, changed Gap Analysis/Desk Audit to document review. Added timing for client submittal of information and corrective actions, and defined possible consequences. Added requirement to review uncertainty budgets that support BMC. Defined information sent to assessors prior to the assessment.
Rev. 4	11/24/01	Lynne Neumann	Clarified the issues around verification of Scope of Accreditation and the laboratories ability to get valid results from all test that appear on their scope.
Rev 5	02/05/03	Robert Levine	Remove references to Guide 25 and Guide 25 related documents
Rev. 6	3/21/03	Lynne Neumann & Thom Adams	Revised use of Form 205.1 to match the process as defined in the revised form. Removed references to Guide25. Clarified language. Updated the method for assessing tests and calibrations to assure that all technologies and parameters are assessed for technical competence.
Rev 7	04-18-03	Charles Ellis	Clarified issues with seeking advice from technical experts to assure standardized practices in the assessment of laboratories.
Rev. 8	11/11/03	Lynne Neumann	Updated to current methods for accreditation and organization structure
Rev. 9	10/21/05	Jason Stine	Combined points of SOP 214, Form 14 and reformatted.
Rev 10	02/06/06	Jason Stine	Added new assessor requirements for multisite site closing meeting
Rev 11	06/12/06	Jason Stine	Clarified multi-site requirements. Updated reference documents. Added assessor requirements for pre assessments. Updated to reflect current practice.
Rev 12	08/03/06	Jason Stine	Added details to the "Activities to be Carried out Prior to Assessment Visit" and added the Assessor Instruction Manual Annex A reference
Rev 13	08/25/06	Doug Leonard	Added part G paragraph 1 section f the reference to Form 001 "Traceability Tracking"
Rev 14	10/24/06	Ryan Fischer	Requirements of in-house calibrations during the technical competence evaluation.
Rev 15	03/01/07	Doug Leonard	Updated section A. 5), F. Assessment Process,. Added reference to Form 001, Form 230, Updated section J. Post Assessment activities

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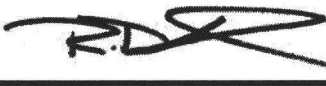
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Rev. 16	05/06/10	Doug Leonard	Added reference to Sector Specific Program documents and the core documents being represented in the SOP in the Scope. Also revised to eliminate unneeded SOP's for assessors as they are replaced with the Assessor Handbook
Rev. 17	09/02/11	Doug Leonard	Added "Within the event letter L-A-B also sends the client an assessor(s) bio(s) with the request for sign off assuring no conflict with the assessor(s)". Added "Submitting the required documentation detailed in L-A-B Form 18 and Form 214.4 and/or the appropriate required documentation as specified per accreditation program (i.e. DoD ELAP, NEFAP, METCAP, CMT LAP, etc.)"

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